

K221121 Volumat Polyethylene I.V. Administration SetJun 16, 2023
424 days to decisionK221121 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k221121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 18, 2022
Decision date	Jun 16, 2023
Days to decision	424 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Kabi
Location	Bad Hersfeld, DE
Contact	Jason Ma
Website	http://www.fresenius-kabi.com/
510(k) history	2 submissions · 2 cleared · 2023-2023

Fresenius Kabi is a global healthcare company specializing in pharmaceutical, nutritional, and medical technology solutions. The company operates with a manufacturing facility in Bad Hersfeld, Germany, and maintains a worldwide presence across multiple regions. Fresenius Kabi has received FDA 510(k) clearances from total submissions. The company's regulatory focus centers on General Hospital devices, with clearances granted in 2023. This represents a historical record of FDA submissions in the medical device space. The company's cleared devices include intravenous adminis...

REGULATORY CONSULTANT

Consulting firm	Fresenius Kabi USA,Llc
Contact	Jason Ma

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k221121/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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